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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/518,098	03/03/00	SHAPIRO	L 114232.107

021269
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HM12/0525

EXAMINER	
LUKTON D	
ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 05/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/518,098	Shapiro
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b)..

Status

1) ☒ Responsive to communication(s) filed on *May 4, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-45* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-45* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

A sequence listing has been provided. However, the sequence on page 2 of the specification has not been included. A CRF listing is required for this as well.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The abreviation "SEMAAT" is used hereinbelow and stands for a "substance exhibiting mammalian α1-antitrypsin or α1-antitrypsin-like activity"

A restriction is imposed. First, however, the following subgenera are defined:

G1: Each and every one of the SEMAAT's must meet at least one of the following conditions:
(a) a chemical name is provided in the specification which identifies the structure of the compound in question;
(b) a trademark name is provided in the specification which uniquely identifies a single compound;
(c) in the case of claims drawn to peptides, sufficient amino acid sequence information that one can tell from the specification what peptides are encompassed (even if there is an infinite number); the peptides of claims 14 and 15 are included, for example. There is a significant caveat, however with regard to peptides, that are described using the "comprising" language. That is, any peptide which would

constitute new matter, were it not for "incorporation by reference", are excluded from G1. By way of example, consider claim 14, and Seq ID No. 1, which is FVFLM. Suppose that a §102(b) reference taught the exact method of claim 9, using the peptide FVFLM. Suppose that in response, applicants reached into one of the references cited in the specification and "extracted out" a new genus of peptides containing FVFLM, such as the following: QRST**FVFLM**WEG and EWCYT**FVFLM**WIHG. These peptides would constitute new matter, were it not for the "fact" (in this hypothetical example) that these two peptides (QRST**FVFLM**WEG and EWCYT**FVFLM**WIHG) are disclosed in a patent or journal article (in this hypothetical example) that has been incorporated by reference. Thus, even though these two peptides are encompassed by claim 14, they are excluded from G1 because they would constitute new matter, were it not for "incorporation by reference".

G2: The SEMAAT's can be whatever the claims permit, provided that G1 is excluded. Included in this group are peptides that would be considered new matter, were it not for the fact that applicants have "extracted out" the peptide in question from a reference. The two hypothetical examples recited in G1 would be included here (QRST**FVFLM**WEG and EWCYT**FVFLM**WIHG). Also included here would be limitations on the length of peptides, which limitations are not disclosed in the specification, but which might be disclosed in a publication that has been "incorporated by reference". For example, with respect to claim 14, suppose that a reference disclosed a genus of compounds exhibiting α1-antitrypsin activity, and disclosed further that peptides comprising SEQ ID NOS. 1-18 are included, and that they should consist of e.g., 15-30 amino acids. If this limitation of 15-30 amino acids is disclosed in a reference, and subsequently "imported" into the specification, but at the same time, this limitation of 15-30 amino acids was not disclosed in the specification as filed, claims which were to incorporate such a limitation would be placed in group "G2". To take another example, suppose that applicants were to amend claim 15 to recite that variables B, D, E and F could not be absent, and that each of I, A, C, G, II must be absent. This could be construed as new matter; applicants, for their part, might then reach into a reference and "extract out" this genus. This new genus, which would be new matter, were it not for the "incorporation by reference", and subsequent importation into the specification, falls within G2.

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Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-26, 28, 29, 30, 31, drawn to a method of treating a viral infection, limited to G1.

2. Claims 1-7, 9-16, 18-26, 28, 29, 30, 31, drawn to a method of treating a viral infection, limited to G2.

3. Claims 27 and 35, drawn to a method of treating a patient who has a deficiency of AAT, limited to G1.

4. Claims 27 and 35, drawn to a method of treating a patient who has a deficiency of AAT, limited to G2.

5. Claims 30 and 32, drawn to a method of treating a disease, with the proviso that viral infections are excluded, limited to G1.

6. Claims 30 and 32, drawn to a method of treating a disease, with the proviso that viral infections are excluded, limited to G2.

7. Claim 33, drawn to a method of inhibiting entry of viral nucleic acid into the nucleus of a mammalian cell, limited to G1.

8. Claim 33, drawn to a method of inhibiting entry of viral nucleic acid into the nucleus of a mammalian cell, limited to G2.

9. Claim 34, drawn to a method of inhibiting exit of a virion from a mammalian cell, limited to G1.

10. Claim 34, drawn to a method of inhibiting exit of a virion from a mammalian cell, limited to G2.

11. Claims 36-39, 43-45, drawn to compositions, limited to G1.

12. Claims 36-39, 43-45, drawn to compositions, limited to G2.

13. Claims 40-42 drawn to drawn to a method of treating a viral infection which includes the use of RT inhibitors and HIV protease inhibitors, limited to G1.

14. Claims 40-42 drawn to drawn to a method of treating a viral infection which includes the use of RT inhibitors and HIV protease inhibitors, limited to G2.

The claimed inventions are distinct.

Clearly, the key issue of concern at this point is that applicants will create genera of specific agents, which genera could not have been predicted from a reading of the specification. This restriction imposes no prohibition on applicants pursuing this option, but the "window of opportunity" for doing this will close after the first Office action on the merits. Moreover, in the event that applicants elect one of the Groups drawn to "G2", the possibility of imposing a second or third restriction after the first Office action on the merits is not precluded.

Claim 30 has been divided into two parts, one is limited to viral infections, and the other encompasses any other disease.

Inventions {11, 12} on the one hand, and the remaining groups on the other hand are related as product and process of use. The inventions can be shown to be distinct if either

or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). Nevertheless, in the event that either of Groups 11 or 12 is elected, the corresponding method-of-use claims will be rejoined for further examination. [*In re Ochiai* (**37** USPQ2d 1127)]. However, in the event that applicants elect either of Groups 11 or 12 a second restriction will be issued. There are dozens, if not hundreds of §102 and 103 art rejections that could be justifiably imposed against claims 36 and 43.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

✱

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800